

## R E M A R K S

The office action of February 7, 2005 has been reviewed and its contents carefully noted. Reconsideration of this case, as amended, is requested. Claims 1 through 30 remain in this case, claims 1, 6, 14, and 19 being amended by this response.

### **Rejection under 35 U.S.C. §112**

Claims 1-30 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to overcome the rejection. More specifically, "chip-to-chip" has been amended to "module-to-module" to provide antecedent basis for this limitation in the claim. In addition, claims 6, 14, and 19 have been amended for consistency. All of the occurrences of "chip" have been replaced with "module" in the claims. No new matter has been added.

Applicant believes that these amendments have fully addressed the Examiner's rejections, and the claims are now in condition for allowance. Reconsideration and withdrawal of the rejection are respectfully requested.

### **Rejection under 35 U.S.C. §102**

Claims 1-9, 11-13, 15, 16, 18-22 and 26-30 were rejected under 35 U.S.C. 102(b) as being anticipated by Purcell (3,548,849). Applicant respectfully disagrees with the rejection.

Purcell is discussed in the present application. "Purcell's US patent no. 3,548,849, "Fluidic Circuit Package", discloses means of stacking fluidic components that provides for the synthesis of a microfluidic circuit. However, the stacking of chips, while making the sealing of the components simpler, eliminates the investigator's ability to monitor the system optically. The stacked scheme also restricts fluid delivery by limiting the available locations for ingress or egress. The purpose of Purcell's work was to provide a means for producing fluidic circuits in

order to replace electronic circuits, not to allow for chemical and biochemical reaction and analysis.” (present application, page 4, lines 3-10).

Claim 1 includes, in part, “an alignment base comprising a plurality of wells”. The Examiner states that Purcell includes “a base structure (208) comprising a plurality of well, reservoir or port structures (215 on element 208).” (present office action dated February 7, 2005, page 2, lines 21-22). Reference numeral (208) in Purcell is a fluidic element. In fact, this structure in Purcell is not a base at all- it is a microfluidic conduit with ports. There is no alignment base in Purcell. Instead, each microfluidic element is a layer of the stacked structure. The fluidic element (208) provides specific circuitry for the system. In addition, the fluidic element (208) does not include wells.

Claim 1 also includes, in part, “a plurality of microfluidic modules having a shape which corresponds to a shape of the wells”. The Examiner states that Purcell includes “a plurality of modules (e.g., 201 & 202)” (present office action dated February 7, 2005, page 2, line 22). Purcell discloses “manifold members 201 and 202 are provided with eight vertical passages, rather than six, for matching the eight ports in the fluidic elements 207 and 208. Again, however, the ports in the fluidic elements 207 and 208 are located and aligned with respect to the manifold ports” (col. 8, lines 16-22). The manifold members in Purcell are planar fluidic elements of the stacked structure. The manifold members in Purcell do not include microfluidic modules that have a shape that corresponds to the shape of the wells.

Even assuming that fluidic element (208) is a base structure (which the Applicant does not concede, see discussion above), that the ports (215) in fluidic element (208) are equivalent to wells (which the Applicant does not concede, see discussion above) and manifold members (201) and (202) are equivalent to the microfluidic modules (which the Applicant does not concede, see discussion above), it is clear that (201) and (202) do not have a shape that corresponds to the shape of the ports (215).

Claim 1 also includes, in part, “a plurality of fluid communication ports located around a periphery of the microfluidic modules”. The Examiner states that the structure in Purcell has “fluidic connection with one another” (present office action dated February 7, 2005, page 2, lines 22-23). Purcell does not disclose a plurality of fluid communication ports located around a

periphery of microfluidic modules. Even assuming that (201) and (202) are microfluidic modules (which the Applicant does not concede, see discussion above), there are no fluid communication ports located around a periphery of these members.

Claim 1 also includes, in part, “such that the microfluidic modules fit into the wells of the alignment base and the fluid communication ports in each microfluidic module overlap adjacent microfluidic modules in at least one location, the overlap allowing the fluid communication ports of adjacent microfluidic modules to be aligned with each other such that there is a direct fluid connection between adjacent microfluidic modules”. Purcell does not disclose microfluidic modules that fit into wells of a base structure. In addition, Purcell does not disclose ports that overlap adjacent microfluidic modules in at least one location. Consequently, Purcell does not disclose overlap that allows the fluid communication ports of adjacent microfluidic modules to be aligned with each other such that there is a direct fluid connection between adjacent microfluidic modules.

Claim 1 also includes, in part, “a cover plate operatively connected to the alignment base, such that when the cover plate is mated with the alignment base, pressure is applied at each periphery location of the microfluidic modules, such that a leak free module-to-module seal is formed”. The Examiner states that Purcell includes a cover plate structure (207). Reference numeral (207) is a fluidic element of the device. It is a microfluidic conduit, not a cover plate.

Since claim 1 includes multiple elements not disclosed in Purcell, claim 1 is not anticipated by Purcell. Reconsideration and withdrawal of the rejection of claim 1 is respectfully requested.

Claim 6 includes “optical access to every microfluidic module, wherein the optical access allows for fluid visualization or molecular detection on each module”. The Examiner states that “Purcell teaches the incorporation of apertures or ports (212) in the cover plate structure (207).” (present office action dated February 7, 2005, page 3, lines 1-2). Purcell discusses reference numeral (212) briefly. “Output port 212 in fluidic element 207 is connected to control port 215 of fluidic element 208 through open seal 260a, passage 210, external conduit 215, (which communicates with passage 210 through a cross-passage in manifold 201) passage 210a in manifold 202, and through an open washer (not shown) in the lower end of passage 210a which

is adjacent and communicates with port 215.” (col. 8, lines 35-42). The output port 212 does not provide optical access to microfluidic modules. Purcell does not disclose optical access that allows for fluid visualization or molecular detection on each module.

Claim 9 includes “wherein the system is reconfigurable”. The Examiner states that reconfigurable is an intended use limitation. However, the reconfigurability of the system is a structural limitation. The system of the present invention can be configured in a totally arbitrary fashion. “The microfluidic breadboard of the invention is not designed to complete a single, specific, predetermined task - rather, the present invention is designed for reconfigurability to allow testing of a variety of potential microfluidic system designs.” (present application, page 4, line 29 to page 5, line 3). In all of the prior art, including Purcell, there is some set fluidic channel footprint to which additional modules are attached. In Purcell, the footprint is provided by fluidic element (208). The pattern of fluidic element (208) provides the specific circuitry of the system desired.

In the system of the present invention, the modules can be positioned in any fashion to build the desired channel structure. There is no set starting point. For example, if Purcell were to build one of his fluidic circuits he would start by machining a set of matching components. Each of his circuits would require a different set of “planar fluidic elements”, with ports in different places and channels connecting them in a special pattern. In the reconfigurable system of the present invention, one would simply position (or reposition) the “building blocks” in the desired manner. The present invention provides complete flexibility - a blank canvas, so to speak. In contrast, Purcell provides a preset motherboard - a line drawing to be colored as the user chooses, but the basic picture is already drawn.

Claim 12 includes “wherein the functional modules perform a biological or chemical function”. Purcell discloses a means for producing fluidic circuits to replace electronic circuits. None of the components disclosed in Purcell perform a biological or chemical function.

Claim 16 includes “wherein the microfluidic modules have a substantially square shape, such that the fluid communication ports are located at least at the corners of the microfluidic modules.” Purcell does not disclose microfluidic modules that have a substantially square shape.

In addition, Purcell does not disclose fluid communication ports located at least at the corners of microfluidic modules.

Claim 19 includes “wherein each microfluidic module further comprises at least two layers”. Purcell does not disclose microfluidic modules comprising at least two layers.

Claims 2-9, 11-13, 15-16, 18-22 and 26-30, being dependent upon and further limiting independent claim 1, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the rejection of claims 2-9, 11-13, 15-16, 18-22 and 26-30 is respectfully requested.

### **Rejection under 35 U.S.C. §103**

Claim 14 was rejected under 35 U. S.C. 103(a) as being unpatentable over Purcell in view of Shaw et al. (6,290,791). Applicant respectfully disagrees. The argument regarding the anticipation of claim 1, upon which claim 14 depends, is repeated herein by reference.

Regarding claim 1, upon which claim 14 depends, Purcell does not teach or suggest all of the elements of the claim. Claim 1 includes, in part, “an alignment base comprising a plurality of wells”. The Examiner states that Purcell includes “a base structure (208) comprising a plurality of well, reservoir or port structures (215 on element 208).” (present office action dated February 7, 2005, page 2, lines 21-22). Reference numeral (208) in Purcell is a fluidic element. In fact, this structure in Purcell is not a base at all- it is a microfluidic conduit with ports. There is no alignment base in Purcell. Instead, each microfluidic element is a layer of the stacked structure. The fluidic element (208) provides specific circuitry for the system. In addition, the fluidic element (208) does not include wells.

Claim 1 also includes, in part, “a plurality of microfluidic modules having a shape which corresponds to a shape of the wells”. The Examiner states that Purcell includes “a plurality of modules (e.g., 201 & 202)” (present office action dated February 7, 2005, page 2, line 22). Purcell discloses “manifold members 201 and 202 are provided with eight vertical passages, rather than six, for matching the eight ports in the fluidic elements 207 and 208. Again, however, the ports in the fluidic elements 207 and 208 are located and aligned with respect to the manifold ports” (col. 8, lines 16-22). The manifold members in Purcell are planar fluidic

elements of the stacked structure. Purcell does not teach or suggest microfluidic modules that have a shape that corresponds to the shape of the wells.

Claim 1 also includes, in part, “a plurality of fluid communication ports located around a periphery of the microfluidic modules”. The Examiner states that the structure in Purcell has “fluidic connection with one another” (present office action dated February 7, 2005, page 2, lines 22-23). Purcell does not, however, teach or suggest a plurality of fluid communication ports located around a periphery of microfluidic modules.

Claim 1 also includes, in part, “such that the microfluidic modules fit into the wells of the alignment base and the fluid communication ports in each microfluidic module overlap adjacent microfluidic modules in at least one location, the overlap allowing the fluid communication ports of adjacent microfluidic modules to be aligned with each other such that there is a direct fluid connection between adjacent microfluidic modules”. Purcell does not teach or suggest these elements of claim 1.

Claim 1 also includes, in part, “a cover plate operatively connected to the alignment base, such that when the cover plate is mated with the alignment base, pressure is applied at each periphery location of the microfluidic modules, such that a leak free module-to-module seal is formed”. The Examiner states that Purcell includes a cover plate structure (207). Reference numeral (207) is a fluidic element of the device. Purcell teaches a fluidic element (207), not a cover plate.

Shaw et al. do not provide what Purcell lacks. Shaw teaches a micro-engineered structure and a capillary tube, as well as a method for connecting the tube to the structure.

Shaw does not teach or suggest an alignment base or a cover plate, as claimed. In addition, claim 1 includes, in part, “a plurality of microfluidic modules having a shape which corresponds to a shape of the wells”. Shaw does not teach or suggest this element of claim 1. Shaw also does not teach or suggest “a plurality of fluid communication ports located around a periphery of the microfluidic modules such that the microfluidic modules fit into the wells of the alignment base and the fluid communication ports in each microfluidic module overlap adjacent microfluidic modules in at least one location, the overlap allowing the fluid communication ports

of adjacent microfluidic modules to be aligned with each other such that there is a direct fluid connection between adjacent microfluidic modules". Therefore, claim 1 is not obvious over Purcell in view of Shaw, alone or in combination.

Claim 14, being dependent upon and further limiting claim 1, should also be allowable for that reason, as well as for the additional recitations it contains. Reconsideration and withdrawal of the rejection of claim 14 is respectfully requested.

#### **Allowable Subject Matter**

Claims 10, 17, and 23-25 were objected to as being dependent upon a rejected base claim, but the Examiner indicated that they would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and rewritten to overcome the rejection under 35 U.S.C. 112, 2<sup>nd</sup> paragraph.

Claim 1 should now be allowable. Claims 10, 17, and 23-25, being dependent upon and further limiting claim 1, should also be allowable for that reason, as well as for the additional recitations they contain. Reconsideration and withdrawal of the objection are respectfully requested.

#### **Conclusion**

Applicant believes the claims, as amended, are patentable over the prior art, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicants' attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

"Recognizing that Internet communications are not secured, I hereby authorize the PTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

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